

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US05/023134

International filing date: 30 June 2005 (30.06.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/658,161
Filing date: 04 March 2005 (04.03.2005)

Date of receipt at the International Bureau: 02 September 2005 (02.09.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

1361334

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

August 25, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 60/658,161

FILING DATE: *March 04, 2005*

RELATED PCT APPLICATION NUMBER: *PCT/US05/23134*



Certified by

Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office

Please type a plus sign (+) inside this box →



Approved for use through 07/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)

Given Name (first and middle (if any))	Family Name or Surname	Residence (City and either State or Foreign Country)
NEIL LOUISE	DUGGAL RAYMOND	LONDON, ONTARIO, CANADA LONDON, ONTARIO, CANADA

☐ Additional inventors are being named on the _____ separately numbered sheets attached hereto
TITLE OF THE INVENTION (280 characters max)

ARTIFICIAL SPINAL DISC

Direct all correspondence to:

CORRESPONDENCE ADDRESS

Customer Number

28079

Place Customer Number
Bar Code Label here

OR

Type Customer Number here

Firm or
Individual Name

Address

Address

City

State

ZIP

Country

Telephone

Fax

ENCLOSED APPLICATION PARTS (check all that apply)

Specification Number of Pages

19



CD(s), Number



Drawing(s) Number of Sheets

5



Other (specify)



Application Data Sheet. See 37 CFR 1.76

Total # of sheets

24

Application Size Fee =

\$0.00

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)

Applicant claims small entity status. See 37 CFR 1.27.



A check or money order is enclosed to cover the filing fees

FILING FEE
AMOUNT (\$)

The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number

50-1641

\$100.00



Payment by credit card. Form PTO-2038 is attached.

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.



No.



Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

SIGNATURE

U. M. Guinness

TYPED or PRINTED NAME

URSULA M. MCGUINNESS

TELEPHONE

905-540-7117

Date

03/04/2005

REGISTRATION NO.

51,377

(If appropriate)

Docket Number:

H310918US

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

P19SMALU/REV07

030405

13281 U.S. PTO

13277 U.S. PTO
60/658161

030405

13281 U.S. PTO
030405

ARTIFICIAL SPINAL DISC

FIELD OF INVENTION

[0001] The present invention relates to methods and devices for the treatment of disc disease and spinal deformities with a disc replacement.

BACKGROUND OF THE INVENTION

[0002] The spine plays an integral role in neural protection, load bearing and motion. The vertebral column provides a strong, yet mobile central axis for the skeleton and is composed of twenty-four mobile vertebral bodies with seventy-five stable articulations. The intervertebral disc is a fundamental component of the spinal motion segment, providing cushioning and flexibility. Adjacent vertebrae are linked together by three articulations: a) the vertebral bodies and disc, which transmit compressive loads and provide flexibility and b) the facet joints, which protect the disc from translational shear stress and limit rotation. This "triple joint complex" allows for flexion, extension, lateral bending and rotation of the spine.

[0003] The structure and function of the discs may be altered by a variety of factors including repeated stress, trauma, infection, neoplasm, deformity, segmental instability and inflammatory conditions. In addition, degeneration of the spine is a universal concomitant of human aging. Cervical spondylosis and aging are intimately related, with spondylosis increasing in both prevalence and severity with age. It has been estimated that almost half of Americans over the age of forty are affected by degenerative disc disease of the cervical spine.

[0004] An intervertebral disc is composed of an inner gel-like matrix called the nucleus pulposus and an outer surrounding annulus called the annulus fibrosus. When compressive loads are placed on the spine, increased pressure in the nucleus pulposus is transmitted to the annulus, which bulges outwards. The degenerative cascade of the intervertebral disc initially involves loss of water from the nucleus pulposus. With decreased cushioning effect from the nucleus, increased loads are transmitted to the annulus and facets. The increase stress on the annulus leads to fissures and radial tears

in its' collagen fibers. With further degeneration, this can lead to circumferential bulging of the disc, contained and uncontained disc herniations, and complete desiccation of the disc. Degenerative disc disease can result in axial pain, by stimulating pain fibers in the annulus, or compression of spinal nerves and/or the spinal cord. This can manifest in weakness, pain and/or numbness in the arm or legs or both.

[0005] The most common type of surgery used in the United States for the treatment of degenerative disorders of the spine (spondylosis) is spinal fusion. In an interbody fusion, the diseased disc is removed and either a wedge of bone from the patient's hip, allograft or a metallic spacer is placed between the vertebrae where the disc was removed and the segment is then immobilized. While this surgery has been successful in eliminating motion, there are disadvantages associated with it. By converting a mobile, functional spinal unit into a fixed, nonfunctional one, fusion results in increased strain patterns at levels immediately adjacent to the fused segment. When a segment of the spine is fused, there is decreased motion and the stresses that would normally be cushioned by that segment are transferred to adjacent segments. This can cause adjacent segment disease. Adjacent segment disease can be defined as a clinical syndrome of symptomatic degenerative changes occurring adjacent to a previously fused motion segment. It has been estimated in retrospective studies as occurring at a relatively constant rate in the cervical spine, as high as 2.9% per year with a projected survivorship rate of 26% at 10 years.

[0006] A more recent alternative to spinal fusion is replacement of the damaged disc with an artificial disc. The rationale for the development of the artificial disc is to prevent adjacent segment disease (ASD). Artificial disc devices can be broadly divided into two categories, those that replace the nucleus only, leaving the annulus and end plates intact and those that involve replacement of the entire disc. Both strategies are directed at restoration of intervertebral function. Prosthetic nuclei are described, for example, in United States Patent Nos. 5,047,055 and 5,192,326. United States Patent

application US2002/0183848 also discloses a prosthetic spinal disc nucleus that has a hydrogel core surrounded by a constraining jacket.

[0007] There are several different types of prosthetic devices designed for replacement of the entire disc available in the market. For example, the Prodisc™ and the Charite™ disc are composites of cobalt chromium endplates with a polyethylene core. The Prodisc is described in United States Patent No. 5,314,477 and the Charite disc is described in United States Patent Nos. 5,401,269 and 5,556,431. The Prestige™ disc is another type of artificial disc that comprises a metal on metal design where two metal segments articulate with each other similar to a ball and socket device. Another type of artificial disc that is gaining popularity is the Bryan™ disc described in United States Patent applications 2004/0098131; 2004/00544411; 2002/0128715. The Bryan disc is a composite artificial disc with a low friction; wear resistant, elastic nucleus that articulates with two anatomically shaped metal plates. Thus far, only the Charite™ disc has been approved for use in the United States.

[0008] While the introduction of artificial discs has led to many successful surgeries, there are still problems associated with the current discs. For example, all the artificial cervical discs that are currently commercially available have a consistent fixed height across the entire disc. Insertion of the artificial disc can lead to focal kyphosis or kyphosis at adjacent segments of the spine.

[0009] Degenerative disc disease is a major source of morbidity in our society and it can lead to serious economic and emotional problems for those afflicted. Thus, there is a need for an artificial disc that can alleviate symptoms and correct deformity (sagittal or coronal or both) of the spine.

SUMMARY OF THE INVENTION

[0010] The present invention addresses the problems associated with the artificial discs of the prior art by providing an artificial disc that provides for correction of spinal alignment deformity.

[0011] The artificial disc of the present invention is useful for the treatment of degenerative disc disease. An artificial disc according to the invention is also useful for correcting spinal deformities such as kyphosis, lordosis, and scoliosis.

[0012] It is an object of one aspect of the invention to provide an improved artificial disc replacement that maintains motion at the operative level and reduces the incidence of adjacent segment disease.

[0013] In one aspect of the invention, the artificial disc incorporates an artificial nucleus having an asymmetrical maximum vertical axis.

[0014] In one preferred embodiment, the nucleus is adapted to provide lordotic correction to a damaged spinal segment. In this case the axis of greatest height is positioned in the anterior half of the nucleus.

[0015] In another embodiment, the nucleus is adapted to provide kyphotic adjustment. In this case, the maximum height axis is positioned in the posterior of the nucleus.

[0016] In yet another embodiment, the asymmetrical nucleus can be used for the treatment of scoliosis. To achieve this, the axis of maximum height is lateral (parasagittal) to the middle of the disc.

[0017] According to one aspect of the present invention, there is provided an artificial nucleus, or core, for use in an artificial disc. The nucleus comprises a core of biocompatible, elastomeric material, having the greatest vertical height either at the central vertical axis or at a vertical axis other than the central vertical axis. An asymmetric nucleus is used as required.

[0018] In one preferred embodiment, the core is spherical or ovoid or egg-shaped, having convex upper and lower surfaces and a non-central maximum height vertical axis. In an alternative embodiment, the nucleus is in the form of a truncated cylinder where the top is cut at a plane that is not parallel to the base. In another preferred embodiment, the disc is essentially circular.

[0019] In another aspect of the invention, a novel type of endplate is provided. Unlike other endplates which require extensive sculpting preparation of the vertebral surface, the present endplates have an essentially flat outer or vertebral – contacting surface that allows them to be easily inserted. In a preferred embodiment, the surface is a semi-round plate having at least one unidirectional keel for anchoring the plate in position. The outer surface of the endplate may be coated with a substance which promotes bony growth to enhance stability of the endplate *in situ*. In one embodiment, the outer (vertebral – contacting) surface and the inner (nucleus contacting) surface are essentially parallel to each other. In another embodiment, the outer surface and the inner surface are non-parallel thereby giving the endplate an essentially wedge like conformation. The orientation of the wide and narrow edges of the wedge can be adjusted to provide various types and degrees of spinal correction.

[0020] In yet another aspect of the invention, a spinal disc prosthesis is provided. The prosthesis comprises an artificial nucleus and at least one endplate. Preferably, the prosthesis comprises a superior endplate for attachment to an upper vertebral member, an inferior endplate for attachment to a lower vertebral member and nucleus adapted to fit between the two endplates. The endplate of the invention has a generally flat surface on the bone contacting side and a cup-like depression on the other side for articulating with the nucleus. A central keel is preferably present in the center of the cup to anchor the nucleus in position. The endplate also preferably includes a stop member to prevent the prosthesis from moving toward the spinal canal. In a preferred embodiment, the nucleus may have a maximum vertical axis that is not at the geometric center.

[0021] In another preferred embodiment the nucleus has an upper surface with an upper receptacle and a lower surface with a lower receptacle. The superior endplate has a downwardly projecting protrusion or anchor that engages the upper receptacle and the inferior endplate has an upwardly extending protrusion or anchor that engages the lower receptacle. The prosthesis maintains an appropriate spatial relationship between adjoining

vertebrae and also permits normal range of motion of the spine. In a preferred embodiment the receptacle comprises a groove open at one end. In a further preferred embodiment, the anchor on the endplate is a central keel. The central keel slides into position in the groove to secure the nucleus.

[0022] This summary of the invention does not necessarily describe all features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other features of the invention will become more apparent from the following description in which reference is made to the appended drawings wherein:

[0024] FIGURE 1A illustrates an artificial disc nucleus with the maximum central axis in the geometric midline of the nucleus;

[0025] FIGURE 1B illustrates an artificial disc nucleus having an asymmetric shape with an offset maximum vertical axis that provides 3° of correction;

[0026] FIGURE 1C illustrates an artificial disc nucleus having an asymmetric shape with an offset maximum vertical axis that provides 6° of correction;

[0027] FIGURE 2 is a top view of one embodiment of an artificial disc nucleus;

[0028] FIGURE 3 is a perspective view of one embodiment of an artificial nucleus;

[0029] FIGURE 4 is a perspective view of another embodiment of an artificial nucleus;

[0030] FIGURE 5 is a perspective view of an outer surface of an endplate;

[0031] FIGURE 6 is a perspective view of an inner surface of an endplate;

[0032] FIGURE 7 is a front view of an endplate;

[0033] FIGURE 8 is a front view of a spinal disc device;

[0034] FIGURE 9 is a side view of the spinal disc device of Figure 8;

[0035] Figures 10A and 10B illustrate an embodiment of an artificial spinal disc prosthesis where the endplates may be adapted for lordotic correction, and Figures 11A, 11B, and 11C illustrate other embodiments where the endplates can be adapted for lordotic correction.

DETAILED DESCRIPTION

[0036] In its proper position, the spine follows natural curves, which promote flexibility. These curves include the cervical, thoracic, lumbar and sacral regions of the spine. Naturally, in order to accommodate a curve, there must be some variation in the height of an intradiscal space. The cervical and lumbar regions are naturally lordotic. At different segments along the spine, there are typically different heights for the intradiscal. In addition, the intradiscal height may be different for different people. Each intradiscal space has an anterior region and a posterior region. Thus a standard artificial disc which maintains the same height from the anterior to the posterior may promote kyphosis, resulting in stress at adjacent segments by compressing either the anterior or posterior. It may also result in an uneven load distribution across the device and cause an excessive amount of relative displacement, wear debris and early failure.

[0037] As used herein, the terms, nucleus and core are used interchangeably to refer to an artificial intravertebral device that replaces a damaged intraspinal disc. The artificial core may be provided alone or in combination with a superior endplate for attachment to an upper vertebra or an inferior endplate for attachment to a lower vertebra or both.

[0038] The terms "upper" and "lower" are used herein to refer to the vertebrae on either side of the disc to be replaced. A "superior" plate is affixed to an upper vertebra and an "inferior" plate is affixed to a lower vertebra.

[0039] The terms vertical and horizontal are used herein relative to a standing human being in the anatomical position. The term "anterior" refers to the region towards the front and the term "posterior" refers to the region towards the back. The term "sagittal" refers to regions on either side of the central midline axis.

[0040] The term "asymmetrical" is used herein to refer to an axis of maximum height that not placed centrally or to a nucleus or spinal disc implant not having its maximum vertical axis placed centrally. In other words, the maximum height is not situated or pivoted at the geometric center so that the disc comprises regions that are not exactly the same in shape or size.

[0041] The present invention provides an artificial disc that comprises a nucleus that is not geometrically symmetrical. The disc may have a maximum vertical axis that is not located at the geometric center of the disc. The maximum vertical axis may be located towards the front of the disc, the rear of the disc or on one side of the disc. The positioning of the maximum vertical height is chosen depending on the type of deformity that needs to be corrected. The present invention provides methods for the treatment of degenerative disc disease, lordosis, kyphosis and scoliosis using an asymmetric artificial disc.

[0042] One advantage of the present invention is that the "nucleus" or core may be easily interchanged and revised. Intra-operatively, instruments can be used to gauge the need for correction and the appropriate implant can be inserted. By introducing correction into the nucleus, the surgeon gets flexibility, ease of insertion and revisability that the other methods do not provide. Artificial discs of the present invention are provided with various degrees of deformity correction. The surgeon chooses a disc having the appropriate correction for the patient. Thus, a method of treating a spinal deformity is provided. The method comprises preparing a spinal segment for implant of an artificial disc, measuring the angle of the intervertebral space, selecting an artificial nucleus having the dimensions of the space, affixing a superior endplate to the upper vertebra, affixing an inferior endplate to the lower vertebra and inserting the selected nucleus between the superior and inferior endplates. Alternatively, the angulation of the disc space may be measured by a spacer and the assembled unit of endplate-nucleus-endplate is inserted in unison. The configuration of the nucleus in this pre-assembled construct is determined by the measurement tools (spacers).

[0043] A major advantage of the present system is that the artificial disc can be more easily and rapidly inserted and the nucleus can be changed. This is especially useful in children and young adults where the alignment of the spine changes over time.

[0044] In a preferred embodiment, an asymmetric nucleus adapted for lordotic correction of the cervical spine is provided. The present invention allows the surgeon to restore cervical lordosis to the cervical spine while maintaining motion. The nucleus is composed of a low friction elastomer such as polyurethane or polyethylene (particularly ultra-high molecular weight polyethylene). It has a generally circular geometric design, with varying degrees of lordosis incorporated into it by an axis of maximum height anterior to the geometric center of the nucleus. The anterior height of the nucleus varies, depending on the extent of lordotic correction needed. The nucleus is available in various lordotic angles, e.g. 0, 3° and 6°, as well as differing heights (e.g., 6 and 8 mm). Before deciding on the final nucleus size, a set of instruments is inserted to gauge the need for lordotic correction.

[0045] The nucleus slides between a superior endplate and an inferior endplate. The nucleus can be maintained in position using various types of connectors. For example, in one embodiment, the convex surface of the nucleus has a midline groove to allow the nucleus to slide into place between the positioned endplates. The central keel on the concave surface of the endplate is received in the groove of the nucleus. It is apparent that other types of connections can be used to maintain the nucleus in position. For example, a tooth and lock system or a pop-in system could be used.

[0046] Several embodiments of the nucleus and artificial disc of the present invention are illustrated in Figures 1 through 11.

[0047] These figures are provided for exemplary purposes and are not intended to limit the scope of the invention. Variations in specific designs are encompassed.

[0048] In one aspect of the invention, correction of spinal segment alignment is provided by an artificial nucleus which is generally spherical or ovoid in

shape wherein the two halves on the arc on either side of a central axis are not symmetrical. In other words, the curvature is not geometrically parallel or symmetric.

[0049] Figures 1A to 1C illustrate various examples of artificial disc nuclei. Figure 1A illustrates a nucleus 10 that has not been adapted for lordotic correction. In this nucleus, the axis 12 of greatest height falls in the center of the disc. In Figure 1B, a nucleus 14 that provides 3° of correction is illustrated. In this embodiment, the maximum height axis 16 is asymmetrical to the geometric center 28 of the disc in the illustration. This nucleus provides for lordotic correction. Figure 1C illustrates another artificial disc nucleus 18 having a greater degree of lordotic correction. In the illustration, the maximum vertical axis 20 is positioned to provide a correction of six degrees. In Figures 1B and 1C, an ovoid embodiments of an artificial nucleus are shown. The nucleus comprises an upper convex surface 22, a lower convex surface 24 and a circumferential wall 26. In the nucleus shown in Figure 1A, where there is no lordotic correction, the maximum vertical height is at the central vertical axis. In the nucleus shown in Figure 1B, the maximum vertical axis 16 is positioned to provide an angle of correction of 3°. In the nucleus shown in Figure 1C, the maximum vertical axis 20 is positioned to provide an angle of correction of 6°. It is clearly apparent that the nucleus can be adjusted to provide various degrees of correction and in certain cases no degree of correction is needed.

[0050] Figure 2 is a top view of one example of a nucleus. This nucleus 40 comprises a central convex region 42 which includes a groove or slot 44. This groove or slot 44 enables the nucleus to slide onto the central keel or anchor of an endplate. While the disc is shown as essentially circular, it is clearly apparent that it may take on other shapes such as an ovoid or ellipsoid shape. It is also clearly apparent that other types of anchor receiving means can be used. For example, the shape of the groove may vary or a snap-in or bayonet type of receptacle can be provided to anchor the nucleus in position.

[0051] For lordotic correction, the nucleus is preferably circular or ovoid or egg-shaped having a non-central maximum vertical axis. Alternatively, the

artificial nucleus may take the form of a truncated cylinder as shown in Figure 3. In one preferred embodiment, the nucleus is essentially circular or asymmetrically spherical. The nucleus 50 has an upper surface 52 that terminates in essentially planar top 54. Means for receiving 56 an endplate anchor are provided on the upper surface 52. The lower surface 58 is typically an inverse of the upper surface. The upper cylindrical surface of the nucleus may be truncated in any direction (i.e. front, rear or side). Either the top (superior) surface or the bottom (inferior) surface may be in the form of a truncated cylinder. In another embodiment, both the top and bottom surfaces are truncated.

[0052] Figure 4 illustrates an artificial nucleus 60 where the upper surface 62 is an asymmetric convex surface. Again, either the top or the bottom or both surfaces may be asymmetric.

[0053] For illustrative purposes, the nuclei in the figures have been shown adapted for lordotic correction. It is clearly apparent that the nucleus can have an asymmetric maximum height at the front, the rear or the side. The asymmetrical nucleus of the present invention can be used to correct for various types of spinal misalignment including sagittal, coronal and rotational deformity.

[0054] The novel corrective nucleus of the present invention may be provided alone or it may be provided in combination with an upper endplate, a lower endplate or both an upper and a lower endplate.

[0055] Figures 5 through 7 illustrate an exemplary artificial endplate 70 that can be used in conjunction with the nucleus to provide a novel artificial disc unit. Depending on the condition of the existing vertebral endplates, it may be necessary to insert one or two artificial endplates. An artificial endplate according to the present invention comprises an inner surface with a concave region for receiving the convex surface of an artificial disc. The outer, or bone contacting, surface is essentially flat. This type of artificial endplate is much easier and quicker to insert than previously known endplates. To accommodate previously known endplates, it was necessary to spend a

significant amount of surgical time to sculpt the vertebrae to the appropriate shape to accommodate the artificial endplate. The flat surface of the present artificial endplate enables it to slide on the surface of the vertebra. Affixing means such as a unidirectional keel provides for immediate fixation. Fixation can be enhanced by coating the outer surface with factors that promote bone interaction.

[0056] Figure 5 illustrates the outer, or bone contacting, surface 72 of an endplate of the invention. The outer surface 72 of the endplate is essentially a plate that may incorporate a suitable biological coating 74, such as calcium phosphate or plasmapore, to promote bony ingrowth for long term stability. Attached to the outer surface are two parasagittal keels 76 which provide immediate fixation to the vertebrae. A stop member 78 is also provided at an edge 80 of the endplate. The stop member prevents the prosthesis from impinging on the spinal canal. This stop member 78 will prevent posterior migration of the endplate into the spinal canal. An essentially semi-circular wall 82 joins the outer surface of the endplate to the inner surface. The thickness of 82 may vary with increased thickness anteriorly, posteriorly or parasagittally as discussed further below. The inner surface 84 is shown in greater detail in Figure 6. The inner surface 84 of the endplate is the surface that articulates with the nucleus. In the embodiment shown in Figure 6, this inner surface has a concave region 86 which receives the nucleus. In the center of the concave region 86 is an anchor 88. This anchor positions the nucleus and prevents it from slipping, and also restricts the amount of motion that can occur. This provides for semi-constrained motion. Figure 7 illustrates a front view of the endplate showing the outer surface 72 having two parasagittal keels 76 and the inner surface 84 having a concave region 86 and a central anchor 88.

[0057] Figures 8 and 9 illustrate another embodiment of the invention. In this embodiment a complete spinal disc prosthesis 90 comprising a superior endplate 92, an inferior endplate 94 and an artificial disc nucleus 96 is provided. The endplates are provided in differing sizes to accommodate differences in anatomy. These may be fabricated of titanium alloy, chrome-

cobalt-molybdenum (CoCrMo), cobalt 28 chromium molybdenum, cobalt chrome, or other materials suitable for spinal prosthetic inserts. The endplates have two distinct surfaces. The outer surface 98 is the surface that contacts the vertebral endplate. The outer surface is essentially flat enabling it to easily contact the surface of the natural vertebral endplate. It is preferably porous and may incorporate a suitable biologic coating, such as calcium phosphate or plasmapore, to promote bony ingrowth for long-term stability. In this embodiment it also has two parasagittal keels 100 that provide immediate fixation. The inner surface 102 of each of the endplates has a concave region 103. This region articulates with the nucleus. In the middle of this concave surface, there is an anchoring protrusion 104 which provides an anchor for the nucleus and restricts translation. Both the superior and the inferior endplates have phalanges 106. The stop member prevents the prosthesis from impinging on the spinal canal. Figure 8 illustrates a front view of the prosthesis and Figure 9 illustrates a side view.

[0058] In another aspect of the invention, spinal deformity can be addressed by providing an artificial spinal disc prosthesis where correction is provided in the endplates. Correction endplates may be provided alone, in combination with a symmetrical artificial nucleus or in combination with an asymmetrical nucleus. Figures 10 and 11 illustrate exemplary embodiments of correctional endplates. The degree of correction can be achieved by altering the inner (nucleus-contacting) side of the endplate or the outer (vertebral – contacting) side of the endplate. As shown in Figure 10, the endplate 110 comprises an outer (bone-contacting) surface 112 and an inner surface 114 and a perimeter wall 116 connecting the outer and inner surfaces. The height of the perimeter wall 116 may vary according to the degree and type of correction required. For example, Figure 10B illustrates an endplate adapted for a greater degree of correction than the endplate of Figure 10A. The positioning of the variable height can be adjusted to treat different conditions such as lordosis, kyphosis or scoliosis. The inner surface may be shaped to receive the nucleus and the height of the endplate can be adjusted according to the degree of correction required. Alternatively, as shown in Figure 11, the outer surface 120 and the inner surface 122 may be essentially planar and the

height is adjusted as the outer and inner surfaces become increasingly non-parallel as a result of variation in the height of the perimeter wall 124. Figures 11A through 11C illustrate increasing degrees of correction. An advantage of having an essentially planar outer, or vertebral – contacting, surface is that the device is easier to insert and requires less operating time to prepare the vertebral surface as compared to traditional artificial disc devices.

[0059] The present invention has been described with regard to one or more embodiments. However, it will be apparent to persons skilled in the art that a number of variations and modifications can be made without departing from the scope of the invention as defined in the claims.

WHAT IS CLAIMED IS:

1. An artificial disc nucleus having an asymmetrical axis of maximum vertical height, providing correction of spinal deformity.
2. An artificial disc nucleus according to claim 1, wherein the axis of maximum vertical height is anterior to the geometric center to recreate spinal lordosis.
3. An artificial disc nucleus according to claim 1, wherein the axis of maximum vertical height is posterior to the geometric center to provide kyphotic correction.
4. An artificial disc nucleus according to claim 1, wherein the axis of maximum vertical height is located parasagittally from the geometric center to correct scoliosis.
5. An artificial disc according to claim 2, wherein the nucleus provides a lordotic correction having an angle selected from the group consisting of 3', 6' 9'.
6. An artificial disc according to claim 5 having a lordotic angle of 3 degrees.
7. An artificial disc according to claim 5 having a lordotic angle of 6 degrees.
8. An artificial disc device comprising:
 - i. an artificial disc nucleus as defined in claim 1; and
 - ii. at least one endplate, said endplate having an outer surface for attachment to a vertebra and an inner surface for securing the nucleus in position.
9. An artificial disc device according to claim 8, comprising a superior endplate and an inferior endplate, wherein the artificial disc nucleus is

secured between the inner surface of the superior endplate and the inner surface of the inferior endplate.

10. An artificial disc according to claim 9, wherein the inner surface is concave.
11. An artificial disc according to claim 9, wherein the inner surface comprises a central anchor.
12. An artificial disc according to claim 11, wherein the nucleus comprises a groove adapted to slidingly engage the central keel.
13. An artificial disc according to claim 9, wherein the outer surface is coated with a coating that promotes bony growth.
14. An artificial disc according to claim 13, wherein the coating comprises calcium phosphate or plasmapore.
15. An artificial disc according to claim 9, wherein the outer surface comprises attachment means for attaching to a vertebra.
16. An artificial disc according to claim 15, wherein the attachment means comprises two parasagittal keels.
17. An artificial disc prosthesis comprising:
 - i. a superior endplate;
 - ii. an inferior endplate; and
 - iii. an artificial nucleus positioned between said superior endplate and inferior endplate,wherein said artificial disc has a relatively greater cumulative height on one side relative to an opposite side.
18. An artificial disc prosthesis according to claim 17 wherein said artificial nucleus has an asymmetric axis of maximum vertical height.

19. An artificial disc prosthesis according to claim 17 wherein at least one of said superior endplate and said inferior endplate is wedge shaped.

20. An endplate for an artificial disc prosthesis, said endplate comprising:

- i. an outer surface;
- ii. an inner surface; and
- iii. a perimeter wall connecting said outer surface and said inner surface.

wherein said peripheral wall has a greater height at one side relative to the opposite side.

21. An endplate according to claim 20, further comprising at least one attachment member on the outer surface.

22. An endplate according to claim 20, wherein said inner surface has an anchor member attached thereto enable the nucleus to be anchored in position.

23. An endplate according to claim 22 wherein the perimeter wall is essentially semi-circular having an arc wall region and a radius wall region.

24. An endplate according to claim 23 comprising a stop member attached to said radius wall region.

25. An endplate for an artificial disc prosthesis comprising:

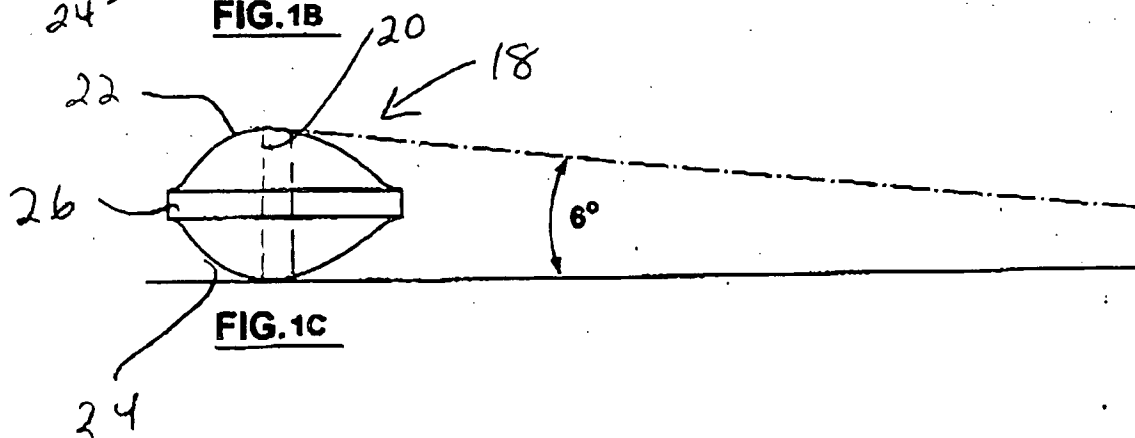
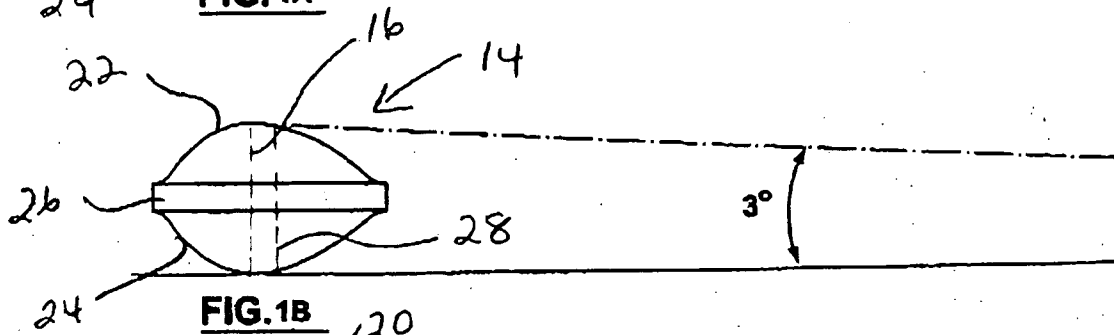
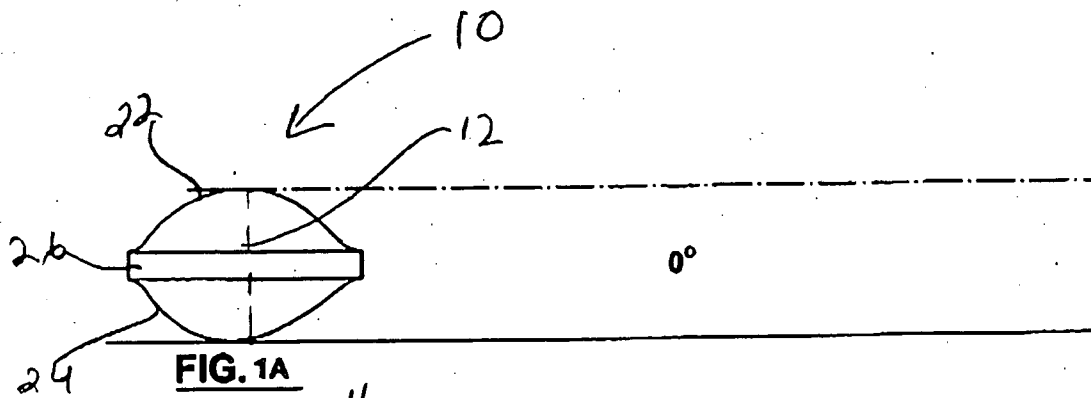
- i. an outer, bone-contacting surface;
- ii. an inner, nucleus-contacting surface; and
- iii. a perimeter wall connecting the outer surface and the inner surface,

wherein the outer surface is essentially planar.

- 26. An endplate according to claim 24, wherein the outer surface comprises at least one attachment member.
- 27. An endplate according to claim 25, wherein the attachment member is a unidirectional keel.
- 28. An endplate according to claim 26 comprising two parasagittal keels.

ABSTRACT

An artificial disc prosthesis is provided. The prosthesis of the present invention enables spinal segment alignment by having a variable height across its surface. The variable height is achieved by an asymmetric artificial nucleus or by at least one variable height endplate.



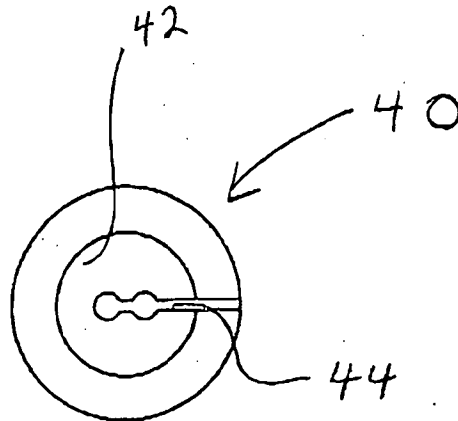


FIG. 2

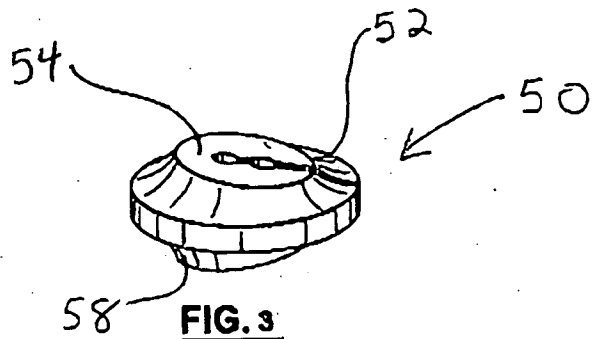


FIG. 3

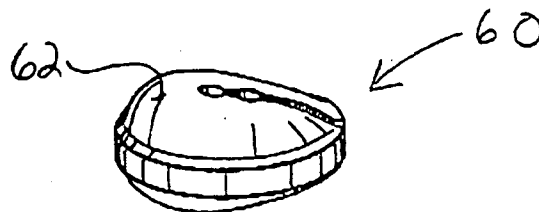
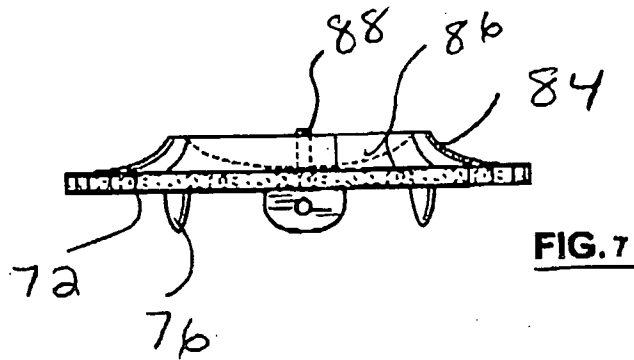
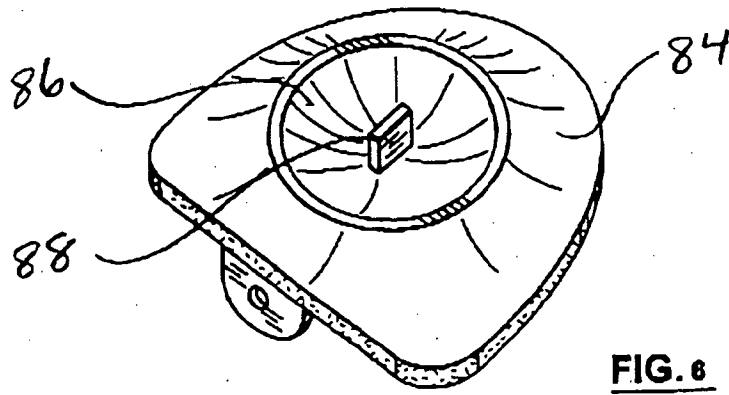
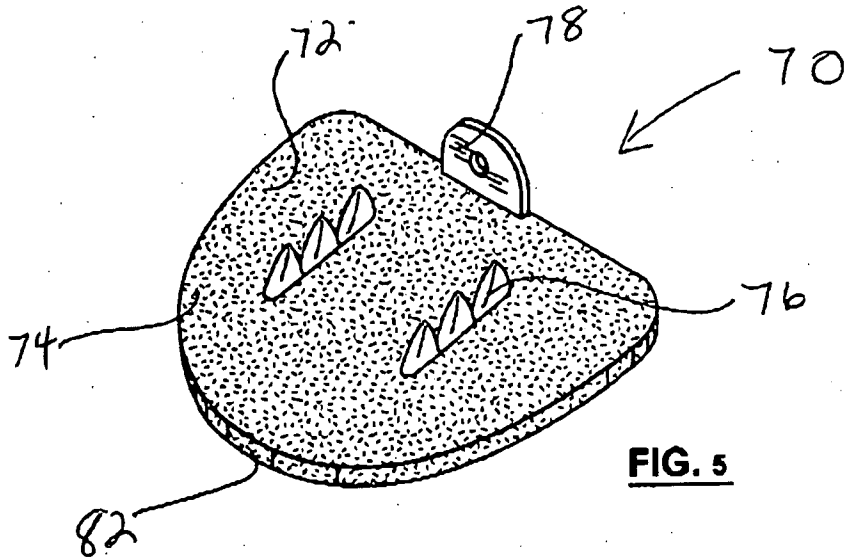
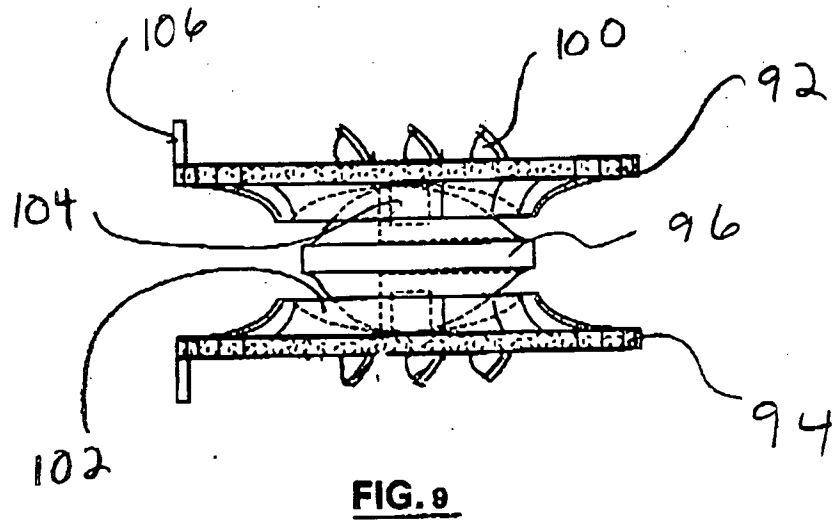
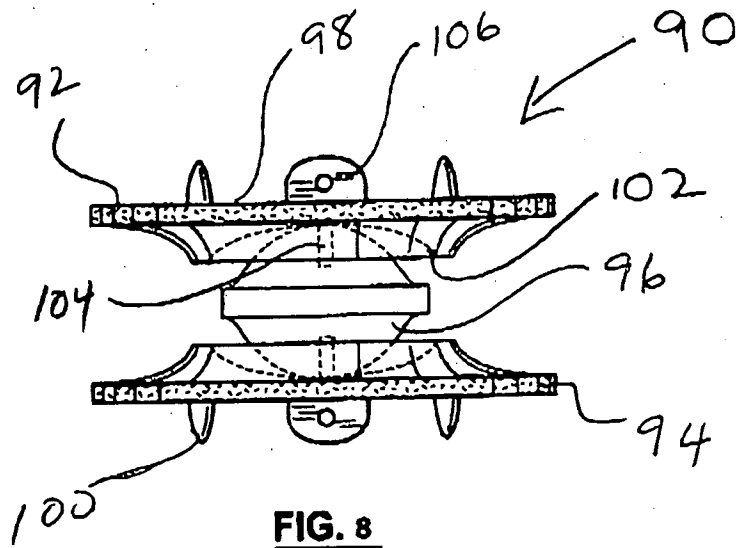


FIG. 4





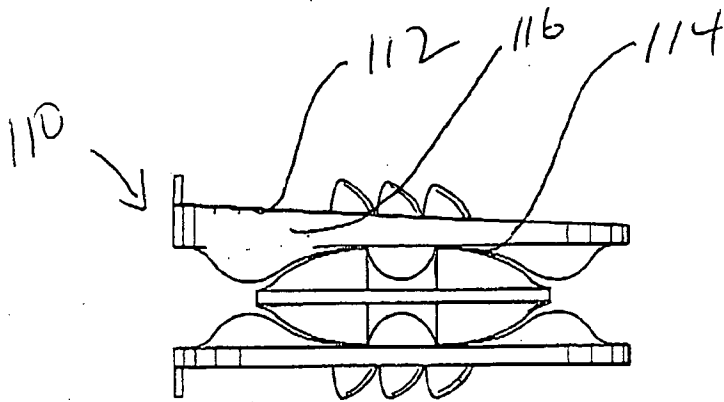


FIG. 10A

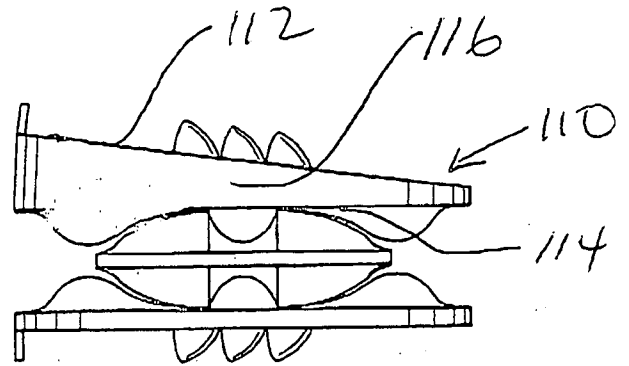


FIG. 10B

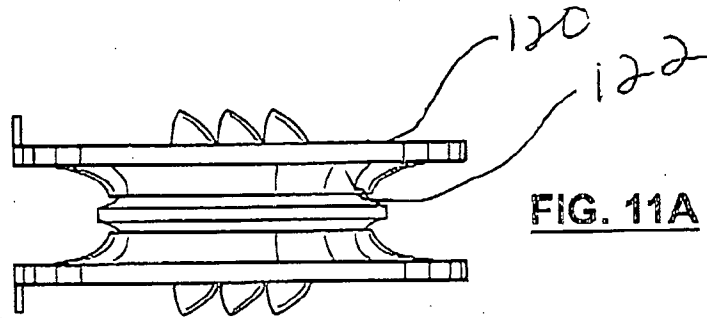


FIG. 11A

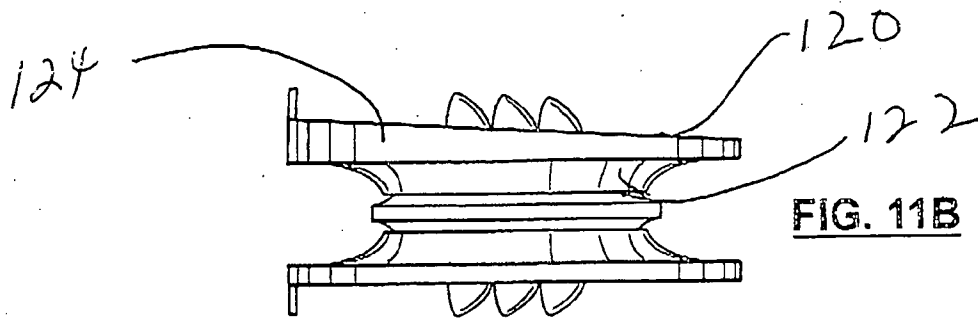


FIG. 11B

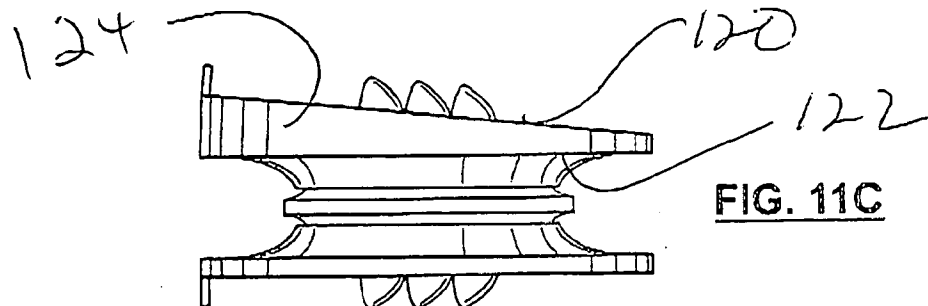


FIG. 11C

INVENTOR INFORMATION

Inventor One Given Name:: Neil
Family Name:: Duggal
Postal Address Line One:: 1544 Gloucester Road
City:: London
State or Province:: Ontario
Country:: Canada
Postal or Zip Code:: N6G 2S6
Citizenship Country:: Canada
Inventor Two Given Name:: Louise
Family Name:: Raymond
Postal Address Line One:: 1544 Gloucester Road
City:: London
State or Province:: Ontario
Country:: Canada
Postal or Zip Code:: N6G 2S6
Citizenship Country:: Canada

CORRESPONDENCE INFORMATION

Correspondence Customer Number:: 28079
Fax One:: 905-528-5833
Fax Two:: 905-523-2509

APPLICATION INFORMATION

Title Line One:: ARTIFICIAL SPINAL DISC
Total Drawing Sheets:: 5
Formal Drawings?: Yes
Application Type:: Provisional
Docket Number:: H310916US
Secrecy Order in Parent Appl.?: No

REPRESENTATIVE INFORMATION

Representative Customer Number:: 28079
Registration Number One:: 51377
Registration Number Two:: 33344
Registration Number Three:: 24969
Registration Number Four:: 50187

Source:: PrintEFS Version 1.0.1